K070220

510(k) SUMMARY

CALCITEC, INC.
OSTEOFIX™ BONE VOID FILLER

APR 12 2007

Sponsor's Name, Address, Telephone Number, Contact Person and Date Prepared

Calcitec, Inc
7000 Bee Cave Road
Suite 250
Austin, TX 78746
Phone: 512-306-9555
Facsimile: 512-306-9557

Contact Person: Brooke Campbell

Date Prepared: January 23, 2007

Name of Device

Osteofix™ Bone Void Filler

Common or Usual Name

Bone Void Filler, Bone Void Filler

Classification Name

Classification: Class II
Classification Name: Filler, bone void, calcium compound

Predicate Devices

- Interpore Cross International, Pro Osteon 500R (K990131)
- Berkeley Advanced Biomaterials, Inc., Cem-Ostetic (K040405)
- Synthes, Norian SRS Bone Void Filler (K011897)

Intended Use / Indications for Use

Osteofix™ Bone Void Filler is indicated for use to fill bony voids or gaps that are not intrinsic to the stability of the bony structure. Osteofix™ Bone Void Filler is intended to be injected into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a Bone Void Filler that resorbs and is replaced with bone during the

healing process.

Technological Characteristics

Osteofix™ Bone Void Filler is a synthetic, injectable, resorbable, Bone Void Filler composed primarily of calcium phosphate, sodium phosphate, deionized water and calcium oxide. The inorganic calcium and phosphorus compounds are incorporated in a compound designed specifically for its resorbability and osteoconductive nature. Osteofix™ kits include sterile powder (calcium phosphate) and solution (dilute sodium phosphate) components. The reactants are packaged in sterile syringes designed to be interlocked to allow the user to mix the two components to form a smooth viscous paste which remains injectable for approximately 6 minutes. Osteofix™ has a working time of approximately 5 to 6 minutes and sets in approximately 4 minutes at body temperature (37°C) after implantation. Osteofix™ Bone Void Filler is progressively resorbed and replaced by host bone during the healing process. The 5cc reactants packs are provided sterile and are for single use only.

Performance Data

The performance of Osteofix™ has been compared to Pro Osteon 500R in a side by side comparison study. Results demonstrated substantially similar rates of resorption of the device material.

Results of bench testing demonstrate that Osteofix™ Bone Void Filler meets its specifications and does not raise new issues of safety or effectiveness. In all instances, Osteofix™ Bone Void Filler functioned as intended.

Biocompatibility Data

Osteofix™ Bone Void Filler was tested in accordance with ISO-10993 in the manner recommended for permanent blood contacting devices, and the materials were shown to be biocompatible. Additionally, the same materials are commonly used in similar medical devices.

Substantial Equivalence

Osteofix™ Bone Void Filler is substantially equivalent to the predicate devices. Osteofix™ Bone Void Filler has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between Osteofix™ Bone Void Filler and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that Osteofix™ Bone Void Filler is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Calcitec, Inc.
% Ms. Brooke Campbell, Esq.
Vice President, Clinical and Regulatory Affairs
7000 Bee Cave Road, Suite 250
Austin, Texas 78746

APR 12 2007

Re: K070220
Trade Name: Osteofix™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class: II
Product Code: MQV
Dated: April 5, 2007
Received: April 5, 2007

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

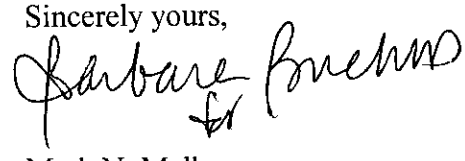
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K070220

Device Name: Osteofix™ Bone Void Filler

Indications for Use:

Osteofix™ Bone Void Filler is indicated for use to fill bony voids or gaps that are not intrinsic to the stability of the bony structure. Osteofix™ Bone Void Filler is intended to be injected into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a Bone Void Filler that resorbs and is replaced with bone during the healing process.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070220